104TH CONGRESS
1ST SESSION

S. 1334

To amend chapter 28 of title 35, United States Code, to provide for noninfringing uses of patents on medical and surgical procedures.

IN THE SENATE OF THE UNITED STATES

OCTOBER 18, 1995

Mr. FRIST introduced the following bill; which was read twice and referred to the Committee on the Judiciary

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A BILL

To amend chapter 28 of title 35, United States Code, to provide for noninfringing uses of patents on medical and surgical procedures.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medical Procedures Innovation and Affordability Act''.

SEC. 2. NONINFRINGING USE.

Section 271 of title 35, United States Code, is amended by adding at the end thereof the following new subsection:

''(j)(1) For any patent issued on or after the effective date of this subsection, it shall not be an act of infringement for a patient, physician, or other licensed health care practitioner, or a health care entity with which a physician or licensed health care practitioner is professionally affiliated, to use or induce others to use a patented technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis. This section does not apply to the use of, or inducement to use, such a patented technique, method, or process by any person engaged in the commercial manufacture, sale, or offer for sale of a drug, medical device, process, or other product that is subject to regulation under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

''(2) For the purposes of this subsection—

''(A) the term 'device' has the same meaning as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h));

''(B) the term 'drug' has the same meaning as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g));

''(C) the term 'health care entity' means a for-profit or nonprofit entity that provides health care services, including a hospital, medical school, health

maintenance organization, group medical practice, or a medical clinic;

''(D) the term 'licensed health care practitioner' means an individual other than a physician who is licensed by a State to provide health care services;

''(E) the term 'patient' means an individual who uses a patented technique, method, or process to self-administer a medical procedure, therapy, or method of diagnosis prescribed or recommended by a physician or other licensed health care practitioner;

''(F) the term 'physician' means a doctor of medicine or osteophathy or a doctor of dental surgery or medical dentistry legally authorized to practice medicine and surgery or dentistry by a State;

''(G) the term 'product' means a machine, manufacture, or composition of matter or improvement thereof;

''(H) the term 'professionally affiliated with' includes privileges, medical staff membership, employment or contractual relationship, partnership or ownership interest, academic appointment, or other affiliation under which the physician or licensed health care practitioner provides health care services (including teaching or instructional services) on be-

half of or in association with a health care entity; and

''(I) the term 'State' means any State or territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.''.

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